Opening Statement of the Honorable Joseph R. Pitts
Subcommittee on Health
Hearing on "Examining the 340B Drug Pricing Program"
March 24, 2015

(As Prepared for Delivery)

Today, we will hear from witnesses about the 340B Drug Discount Program.

Section 340B of the Public Health Service Act (PHSA) requires drug manufacturers, who wish to participate in Medicaid, to provide discounted outpatient drugs to eligible health care organizations known as "covered entities" who serve uninsured, low-income populations.

This program, designed to stretch scarce federal dollars, is critically important for indigent and low-income patients who may otherwise be unable to access needed drugs or afford treatment.

Eligible covered entities are defined in statute and include HRSA-supported health centers and look-alikes, Ryan White clinics and State AIDS Drug Assistance programs, Medicare/Medicaid Disproportionate Share Hospitals, children's hospitals, and other safety net providers.

The Health Resources and Services Administration (HRSA), the agency that administers the 340B drug discount program, indicates that approximately 11,000 covered entities currently participate in the program, with more than one in three hospitals participating. Some 800 or more manufacturers also participate in the program.

Although the program was created in 1992, recent years have seen significant changes and expansions of the program.

For example, from 2001 to 2011, the number of covered entities roughly doubled. Since HRSA issued guidance related to contract pharmacies in 2010, their use in the program has grown exponentially.

Today we will hear from three witnesses who are experts on the program. The witnesses from GAO and the Inspector General's office have both helped author reports advising Congress on the program, and continue to monitor HRSA's management of the program.

GAO and OIG have reported that unclear program guidelines and inconsistent oversight is partially responsible for some of the challenges the program currently faces in being accountable to taxpayers, patients, and stakeholders. Covered entities and manufacturers understandably cannot comply with rules that are unclear.

We benefit today from hearing directly from HRSA about the agency's day-to-day work to respond to the findings of those reports as they seek to more effectively oversee and efficiently operate the 340B program. HRSA has taken steps and made improvements in recent years, so we are glad they can be here today. Recent developments have hamstrung their ability to promulgate regulations to better manage the program, so we look forward to hearing from them.

One thing I hope we can all agree on, is that to preserve the 340B program and ensure that it is serving those who most need help, greater oversight and transparency is needed to increase the program's accountability. Today's hearing marks the first step in that direction.

I would like to welcome all of our witnesses today. We look forward to your testimony on this important subject.

###